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SUGHRUE MION, PLLC			DEES, NIKKI H	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/520,786	<b>Applicant(s)</b> LEADBEATER ET AL.
	<b>Examiner</b> Nikki H. Dees	<b>Art Unit</b> 1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

#### Status

- 1) Responsive to communication(s) filed on 08 August 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2 and 4-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2 and 4-71 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1668)  
 Paper No(s)/Mail Date 08 August 2008.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. The amendment filed August 8, 2008, has been entered. Claims 1, 2, and 4-71 are currently pending in the application. The previous objections to misnumbered claims and claims 10, 27, 29, 68, and 70 have been withdrawn in view of the amendments to these claims. The previous 112 rejection of claims 8 and 46 have been withdrawn in view of the amendments to claims 8 and 46. The previous 102 rejection of claims 20-22 over Beringer et al. has been withdrawn in view of Applicant's arguments. The previous 102 rejection of claims 53, 55, 57-59, 61-64, and 67-70 over Beringer et al. has been withdrawn in view of Applicant's amendment to claim 53. The previous 103 rejection of claims 46-52 and 54 over Beringer et al. in view of Fisher et al. has been withdrawn in view of Applicant's amendments to claims 46 and 53.

***Claim Objections***

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the lower limit of the weight percent range for the gum base in claims 31, 32, 44, 51, 58, and 59 is not supported in the specification (p. 4 lines 1-6).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 claims a tabletted chewing gum sweet having several layers. It is unclear how many layers "several" is meant to encompass.

5. Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 65 claims that the chewing gum tablet comprises a "dental vehicle." The examiner understands "dental vehicle" as a composition used to deliver desired components to the oral cavity including the teeth. The chewing gum tablet itself may act as a "dental vehicle," but will not contain a dental vehicle. The examiner will interpret the claim as a chewing gum table containing an agent with anti-dental caries activity.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4, 12, 14-19, 23-34, 36, 37, 39-41, 43, 44, and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Beringer et al. (4,139,589).

8. Beringer et al. teach a chewing gum product in the form of a multilayered tablet and process for making the tablet (Abstract). The layers are compressed to form a joint tablet comprising at least one tablet mass and one chewing gum mass (col. 1 lines 31-34). Their Example 2 teaches a three-layered tablet with the middle layer comprising a gum base (chicle gum) and tablet base (sugar), as well as two outer layers comprising a tablet base (sorbitol). The gum base is present at about 60 % in Example 2 (col. 8). The layers are taught as being arranged one on top of another, as well as completely enclosed (Figs. 7-8). Beringer et al. further state that the different layers of their product may have different substances mixed in and/or be different colors (col. 4 lines 8-12). The tabletted product may also comprise an active ingredient including pharmaceuticals (col. 1 lines 26-34). The active ingredient (eucalyptus oil) is taught in the second material in Example 2. As the product comprises sugar, it is considered to contain a nutritive (caloric) ingredient. These teachings anticipate Applicants' claims 1-4, 12, 14, 15, 17-19, 25-34, 36, 37, 39-41, 43, 44, and 71.

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9. Beringer et al. state that their product may have one layer that is hard and one layer that is plastic (col. 1 lines 31-34). This would result in an initial crunchy then chewy sensation, thus anticipating Applicants' claim 16.

10. Beringer et al. also prepare their layered tablet with an indentation. The first layer is compressed with an indentation. The second part (gum base) is added to the material. An additional layer is fed into the press and compressed to cover the plastic mass (gum base) inserted in the center (Fig. 6 and col. 5 lines 7-17). These teachings anticipate Applicants' claims 23 and 24.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 5-7, 13, 20-22, 35 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589).

13. Beringer et al. teach a layered tablet chewing gum as applied to claims 1, 25, and 39 above.

14. Beringer et al. are silent as to the layers having a different thickness and to the gum base material and tablet base material being particulated before being combined.

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15. Regarding claims 5-7, 13, 35, and 42, it would have been obvious for one of ordinary skill in the art at the time the invention was made to have varied the thickness of the layers as taught by Beringer et al. in order to provide more (or less) of one of the components of the tablet. As the thickness of the layers may be varied, the weight ratio of the layers may also be varied. The tablet as taught by Beringer et al. could be easily modified by one of ordinary skill without undue experimentation. There would have been a reasonable expectation that the resulting tablet would maintain its favorable chewing gum properties.

16. Regarding claims 20-22, Beringer et al. teach a process for making their layered tablet. The chewing gum base may be mixed with the tablet base (Example 2, col. 8). The tablet mass is granular and pelletized. The granulate gum base is then pressed to the plastic (tablet base) portion of the tablet (col. 2 lines 3-11). Additional layers may be added as shown in Fig. 10 and col. 6 lines 30-45.

17. In the process of Beringer et al., the gum base and tablet material are mixed, granulated, and then compressed. Applicant's claims are to the particulated gum base and particulated tablet material presented separately, mixed, and then compressed. The selection of any order of performing process steps is considered to be *prima facie* obvious in the absence of new or unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946). In the instant case, both the method of Beringer et al. and the claimed method result in a particulate material that is compressed into a tablet. As this result is neither new nor unexpected, the claimed process is considered to be obvious over the prior art.

18. Claims 8-10, 53, and 55-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589) in view of Cherukuri et al. (4,753,805).
19. Beringer et al. teach a chewing gum product in the form of a multilayered tablet and process for making the tablet (Abstract). The layers are compressed to form a joint tablet comprising at least one tablet mass and one chewing gum mass (col. 1 lines 31-34). Their Example 2 teaches a three-layered tablet with the middle layer comprising a gum base (chicle gum) and tablet base (sugar), as well as two outer layers comprising a tablet base (sorbitol). The gum base is present at about 60 % in Example 2 (col. 8). The layers are taught as being arranged one on top of another, as well as completely enclosed (Figs. 7-8). Beringer et al. further state that the different layers of their product may have different substances mixed in and/or be different colors (col. 4 lines 8-12). The tabletted product may also comprise an active ingredient including pharmaceuticals (col. 1 lines 26-34). The active ingredient (eucalyptus oil) is taught in the second material in Example 2. As the product comprises sugar, it is considered to contain a nutritive (caloric) ingredient.
20. Beringer et al. are silent as to the same sugar or polyol being used as the tablet base in both the first (gum base) and second (outer layer) of their invention. Beringer et al. are silent as to the use of a plasticized rubber or polymer for the gum base. They are also silent as to their invention containing a dental vehicle or breath freshener.
21. Cherukuri et al. teach a tabletted chewing gum composition that is made by compression (Abstract). Their invention is taught with both a nutritive sweetener (sugar)

and sugar-free using sorbitol (col. 11 Examples IV and V). Cherukuri et al. teach a number of compounds that may be used for the gum base including polymers (col. 6 lines 14-20). They also teach their invention comprising fluorides for tooth decay (col. 9 lines 34-35) and flavoring agents including spearmint oil and oil of wintergreen (col. 8 line 1).

22. Regarding claims 8 and 10, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a polyol as taught by Cherukuri et al. along with gum base, as well as in the outer layers as taught by Beringer et al. Beringer et al. teach the use of sorbitol in the outer layer (Example 2) and Cherukuri et al. teach the use of sorbitol blended with the gum base for the production of a tabletted chewing gum. One of ordinary skill desiring to produce a sugar free product would be able to substitute sorbitol for the sugar in the invention of Beringer et al. This would not have required undue experimentation on the part of the artisan, and the resultant sugar-free product would have been expected to maintain its favorable taste and chewing properties.

23. Regarding claims 9 and 53, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized a chewing gum base other than the chicle as taught by Beringer et al. One of ordinary skill would have been familiar with other gum bases as taught by Cherukuri et al. and would have been able to substitute a different gum base for the chicle without undue experimentation in order to impart the desired "chewiness" in their product. There would have been a reasonable

expectation that the resultant product would have maintained its favorable chewing properties.

24. Regarding claims 65-66, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the flavoring agents and fluorides to prevent tooth decay as taught by Cherukuri et al. with the chewing gum composition as taught by Beringer et al. The composition of Beringer et al. is taught comprising other pharmaceutical agents, though not the specific ones as claimed. One of ordinary skill could have taken the additional components as taught by Cherukuri et al. and added them to the composition of Beringer et al. without undue experimentation. The resultant product would have been expected to have the desired dental vehicle or breath freshening properties while still maintaining its favorable chewing and taste properties.

25. Claims 11, 38, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589) in view of Fisher et al. (4,370,350).

26. Beringer et al. teach a layered tablet chewing gum product as applied to claims 1, 25, and 39 above.

27. Beringer et al. are silent as to the particle size of the gum base material and tablet base material.

28. Fisher et al. teach a tabletted chewing gum product made by compression (col. 1 lines 65-67). They go on to state that the particles being compressed passed through a

20 to 80 mesh screen (177 µm to 841 µm) and easily tableted on conventional machinery (col. 4 lines 56-58).

29. Regarding claims 11, 38, and 45, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the particle size as taught by Fisher et al. for the production of the tabletted chewing gum product of Beringer et al. The products are being produced by the same technology, and Fisher et al. state that they have favorable results when tabletting their product. Therefore, it would have been obvious to use the same particle size in the layered product of Beringer et al. There would not have been undue experimentation required to make this modification to the product of Beringer et al., and the resultant tablets would have been expected to maintain their chewing and flavor characteristics.

30. Claims 46-52 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beringer et al. (4,139,589) in view of Cherukuri et al. (4,753,805) and in further view of Fisher et al. (4,370,350).

31. Beringer et al. in view of Cherukuri et al. teaches a gum base in the form of polymers as detailed above.

32. Beringer et al. in view of Cherukuri et al. is silent as to the size of the particles to be compressed.

33. Regarding claims 46-52, the product of Beringer et al. is taught as having multiple layers of the same thickness as detailed above. The product also comprises

about 60% of gum base (chicle) and the layers may be different colors, also as detailed above.

34. Beringer et al. are silent as to the particle size of the gum base material and tablet base material.

35. Fisher et al. teach a tabletted chewing gum product made by compression comprising particles ranging in size from 20 to 80 mesh (177  $\mu\text{m}$  to 841  $\mu\text{m}$ ) as noted above.

36. Motivation for combining Beringer et al. and Fisher et al. in respect to claims 46-52 and 54 is the same as the motivation as applied above to claims 11 and 38. One of ordinary skill in the art would have expected this combination to result in a favorable chewing gum tablet.

37. Regarding claim 49 and the varying of the thickness of the layer, motivation for the variations in these thicknesses are the same as applied to claims 5-6 above. The adjustment of the thickness of the layers would not have required undue experimentation, and would not have adversely affected the efficacy of the product.

#### ***Response to Arguments***

38. Applicant's arguments filed August 8, 2008 have been fully considered but they are not persuasive with regard to the 112 rejections of claims 39 and 65. The amendments to claim 39 have not addressed the 112 rejection, and there are no amendments to claim 65 to clarify the term "dental vehicle." The 112 rejections of

claims 39 and 65 stand as previously presented. The arguments are not persuasive with regard to the 102 rejections of claims 1-4, 12, 14-19, 23-34, 36, 37, 39-41, 43, 44, and 71 over Beringer et al., or the 103 rejections over Beringer in view of Cherukuri and Fisher.

39. Applicant's arguments, see Remarks p. 18, filed August 8, 2008, with respect to the rejection(s) of claim(s) 20-22 under 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Beringer et al.

40. Regarding the 102 rejection over Beringer et al., Applicants argue (Remarks, p. 18) that Beringer does not disclose the formation of the gum part from particulated gum base and particulated tablet base.

41. This argument is not convincing with regard to the product claims 1, 25, and 39 as the teachings of Beringer et al. indicate a compressed mixture of particulated gum base material and particulated tablet base material. The material that is compressed by Beringer is a mixture of gum base and tablet base that has been particulated, resulting in a mixture of particulated gum base material and particulated tablet base material. The claims as written do not require that the gum base material and particulated tablet base material be presented separately as particulated materials to be mixed before compressing.

42. Regarding the 102 rejection over Beringer et al., Applicants argue (Remarks, pp. 18-19) that the chicle taught by Beringer teaches away from the present invention as chicle is "plastic" not both "plastic" and "elastic."

43. In response, it is noted first that there is no requirement in the rejected claims that the gum base be both plastic and elastic. Claim 9, for example, which limits the gum base, was rejected over Beringer in view of Cherukuri, with Cherukuri teaching gum bases including polymers. Additionally, Applicants arguments support the Examiner's rejection wherein it is stated that it would have been obvious for one of ordinary skill in the art at the time the invention was made to have selected a gum base other than chicle for use in the invention of Beringer. Applicants argue that one of ordinary skill in the art at the time the invention was made would not have selected chicle for use as a gum base due to its lack of elastic properties. As stated in the rejection, one of ordinary skill would have been able to select a gum base other than chicle as there are many gum bases known in the art and one of ordinary skill would have been able to select the appropriate base to achieve the desired properties in the final composition without undue experimentation.

44. Applicants argue (Remarks, pp. 19-20) that the gum base of Beringer is not present in the amount presented by the Examiner.

45. Applicant's claims 12, 32, 44, 51, and 57-59 are to a gum base present in varying amounts, ranging from 5% to 99%, with all claims encompassing the amount 50% to 99%. The claims to the gum base claim the percentage in the "first integral part" or "said one layer," not in the entire composition. The examiner considered the middle

layer of Beringer to be the “first integral part” or “said one layer” and calculated the amount of chicle gum to be 60% of the 2.82 parts total of the middle layer. The arguments presented by Applicant calculate the amount of chicle gum present in the entire composition of Example 2. This calculation is not in agreement with Applicant's claims and is therefore not considered to be persuasive.

46. Applicants argue that an integral part of chewing gum material is not the result of the invention of Beringer (Remarks, pp. 20-21).

47. In response it is noted that Examples 1 and 2 of Beringer state that the chewing gum portion of the invention remains long after the medicament portion has been administered, leading one of ordinary skill to consider the chewing gum portion of Beringer's invention an integral portion.

48. In response to the 103 rejections over Beringer in view of Cherukuri, Applicants argue that Beringer and Cherukuri cannot be combined as Cherukuri teaches a single-layer gum and does not mix the particulated gum base with particulated tablet base prior to compression (Remarks, p. 21).

49. As indicated above with regard to claims 1, 25 and 39, the claims as written do not require that the gum base and tablet base be particulated before being combined and then compressed. The mixing of the gum base and tablet base, followed by particulation and compressing results in a mixture of particulated gum base material and particulated tablet base material that is subsequently compressed.

50. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

51. Cherukuri is combined with Beringer to show the use of gum bases other than chicle, as well as the addition of different flavors to gum products. The teachings of Cherukuri to a single-layer gum product would not have prevented one of ordinary skill from employing gum bases and flavors as taught into gum products of more than one layer.

52. Applicant further argues that the tablet base material has to form individual compressed particles within the first integral part (Remarks, p. 22)

53. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., individual compressed particles) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

54. The material that is compressed is a mixture of gum base material and tablet base material. This mixture is taught by both Beringer et al. and Cherukuri et al.

55. Regarding the 103 rejections over Beringer et al. in view of Fisher et al., Applicant argues that Fisher does not describe a complete tablet and does not teach a mixture of particulated gum base material and particulated tablet base material (Remarks, p. 23).

56. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

57. It is noted that Fisher et al. was relied upon to teach the appropriate particle size for compression. Fisher et al. state that the particle size of 20 to 80 mesh (177  $\mu\text{m}$  to 841  $\mu\text{m}$ ) lends itself to easy tabulation for chewing gum products (col. 4 lines 56-60). One of ordinary skill would expect that the particle size for tabulation that works well in products of one layer would also provide acceptable results for products of more than one layer.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571) 270-3435. The examiner can normally be reached on Monday-Friday 7:30-5:00 EST (second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on (571) 272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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